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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF UTAH

**ERICA DEAN, EMILY MONROY, KATIE
GIBSON individually, and ASHLEY
PARIS, individually and as next friend of
the Estate of ED WILSON GIBSON,**

Plaintiffs,

v.

SANDOZ, INC.

Defendant.

COMPLAINT

(Jury Trial Demanded)

Civil No. 2:16-cv-00444-DBP

Honorable Dustin B. Pead

Come Now ERICA DEAN, EMILY MONROE, KATIE GIBSON individually, as heirs to Ed Gibson, and ASHLEY PARIS individually as heir to Ed Gibson, and as the next friend of the Estate of ED WILSON GIBSON, herein referred to as Plaintiffs, in the above numbered and styled case, and complains of SANDOZ, INC. (hereinafter “Sandoz” and/or “Defendant”), Defendant, and for cause of action will show to the Court as follows:

INTRODUCTION AND NATURE OF ACTION

1. ED WILSON GIBSON, (hereinafter “Ed,” “Ed Gibson” or “Gibson”) was an individual who resided in Eagle Mountain, Utah. This cause of action is brought on behalf of the estate of Ed Gibson and on behalf of Erika Dean, Emily Monroy, Katie Gibson, and Ashley Paris individually, by the trustee Ashley Paris, in her individual capacity as next of friend of the estate of Ed Gibson. Ed Gibson was prescribed, purchased, and ingested the drug Amiodarone (described more fully herein), which was manufactured and/or sold or distributed by Defendant, and as a proximate cause thereof, Ed Gibson suffered severe and debilitating injuries to his pulmonary system, resulting in his slow and painful death as a result of taking said drug. Ed Gibson’s surviving heirs hereby file this complaint as a result of Defendant’s wrongful conduct.

2. ASHLEY PARIS, is an individual who resides in Draper, Utah. This cause of action is brought on behalf of ASHLEY PARIS, ERICA DEAN, EMILY MONROE, and KATIE GIBSON, as heirs of Ed Gibson. Ed Gibson was prescribed, purchased, and ingested the drug amiodarone (described more fully herein), which was manufactured, promoted and/or sold or distributed by Defendant and as a proximate cause thereof, Ed Gibson suffered severe and debilitating injury to his pulmonary system resulting in permanent damage to Ed. Ashley Paris, Erika Dean, Emily Monroe, and Katie Gibson have endured pain and suffering as a result of Ed Gibson’s death, they have suffered the loss of Ed Gibson’s care, companionship, and guidance. They have also endured the cost of medical and funeral expenses. Collectively, they file this complaint as a result of Defendant’s wrongful conduct.

3. Ed Gibson suffered from bilateral infiltrates and Amiodarone pulmonary toxicity and death as the direct result of consuming a product, Amiodarone, which was manufactured,

supplied, sold, and distributed by the Defendant.

4. Amiodarone is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, manufactured and distributed by the Defendant. Prescription, medical records and the NDC Number of the tablets prescribed and ingested by Ed Gibson all confirm Gibson consumed amiodarone; more particularly the amiodarone manufactured by Sandoz, Inc., actively promoted for “off-label” use by Sandoz and provided to Ed Gibson without the mandated Mediation Guide.

5. Ed Gibson was diagnosed with atrial fibrillation.

6. Defendant’s scheme involved and continues to involve a calculated and deceitful sales and promotional campaign to include paid physician to physician interactions specifically designed to be seen as unbiased information, and an equally egregious failure and refusal to take required, timely, and accurate corrective actions and notice to medical professionals and consumers to prevent catastrophic injury and death to its customers, such as Ed Gibson. Defendant Sandoz additionally benefited from the scheme and continues to do so and supports the scheme by the continued sale of amiodarone for “off-label” use by atrial fibrillation patients such as Gibson.

7. Defendant, like many other drug companies, has spent and spends millions of dollars each year to persuade doctors to prescribe their particular drugs. More particularly, Defendant spent time and money promoting the use of amiodarone “off-label” for patients with atrial fibrillation such as Gibson. There are, however, strict FDA regulations about the form and content of such promotion. In fact, it is unlawful for a manufacturer to promote any drug for a use not described in the approved labeling of the drug. Defendant, by various sales efforts,

continued to promote the sale of amiodarone without concern for unapproved uses and more particularly concern for patients with atrial fibrillation. Defendant's scheme of promoting the use of amiodarone for "off-label" atrial fibrillation has been so pervasive and insidious so as to wrongfully influence medical professionals.

8. The purpose of the federal regulations¹ and requirements governing prescription drugs is to protect patients by ensuring drug manufacturers subject prospective uses of their drugs to randomized and well-controlled clinical trials. The purpose of such trials is to determine whether the drug is safe and effective for such uses, at least when sufficient promise lies to make the cost of such randomized trials worth incurring. These requirements are meant to ensure that drug companies like the Defendant's, give physicians and medical personnel trustworthy unbiased information to use in making prescribing decisions, so that medications are prescribed and branded appropriately and with adequate and up to date warnings.

9. A manufacturer's duty to test a use arises, under both common law and federal law, particularly when the manufacturers learn of any adverse events concerning its sale.

10. As described in further detail herein, in 1985, the initial manufacturer and distributor in the United States or "brand" manufacturer, Wyeth, received FDA approval to market and sell amiodarone only as a drug of last resort for patients suffering from documented recurrent life-threatening ventricular fibrillation and ventricular tachycardia; and further, only such use when these conditions would not respond to other available anti-arrhythmic drugs and

¹ 21 U.S.C. §§ 331(d), 352(f), and 355.

therapies.²

11. Defendant was aware that Wyeth hired agents and embarked on a course of conduct, the purpose of which was to increase amiodarone sales as an initial, first-line anti-arrhythmic medication, a use for which amiodarone has never received FDA approval; i.e., an “off-label” use.

12. Defendant knew of the extreme dangers and catastrophic injuries and death caused by amiodarone, known through adverse events reporting, customer and physician communications, and other sources, which existed for years, when the Defendant entered the market with amiodarone products.

13. Upon information and belief, Defendant recognized a significant profit potential in the dangerous “off-label” promotion and sale of amiodarone as a first-choice cardiac drug for non-life threatening heart ailments; particularly atrial fibrillation, a much more common non-life threatening illness impacting millions of individuals.

14. The Defendant tracked and had full knowledge of the number of prescriptions written for amiodarone to be given as a first-line cardiac drug, and has, through various means, designed to conceal their involvement, promoted and conspired together and with others to promote the use of amiodarone as an initial, first-line therapy for all arrhythmias and other heart ailments.

15. Defendant’s scheme was implemented and enabled Defendant to eventually tap into the enormous market for amiodarone in the United States.

16. Upon information and belief, and at all material times hereto, Defendant was

² See NDA 18-972, Approval Letter, December 24, 1985.

aware from multiple sources, that many of Defendant's amiodarone prescriptions were, and are currently, written for "off-label" purposes, i.e., for the purpose of controlling non-life threatening atrial fibrillation.

17. Defendant's scheme, described in more detail below, ultimately deceived physicians, pharmacists, and consumers into believing that prescribing and taking amiodarone for the "off-label" atrial fibrillation uses that Defendant promoted was appropriate even though Defendant knew FDA approval had not been granted for those uses and, moreover, there was significant medical-scientific evidence indicating amiodarone was very dangerous in those situations, and in fact, resulted in serious pulmonary illness and toxicity, and death, when so used.

PARTIES

18. Plaintiff Ed Gibson was a 68-year-old resident of Eagle Mountain in Utah County Utah. Ed Gibson died at Intermountain Medical Center in Murray, Utah on September 23, 2014.

19. Plaintiff Ashley Paris is a resident of Draper in Salt Lake County Utah. She is the daughter of Ed Gibson, and the trustee to his estate.

20. Plaintiff Erika Dean is a resident of Sandy in Salt Lake County Utah. She is the daughter of Ed Gibson.

21. Plaintiff Emily Monroy is a resident of Sandy in Salt Lake County Utah. She is the daughter of Ed Gibson.

22. Plaintiff Katie Gibson is a resident of Fountain Valley in Orange County California. She is the daughter of Ed Gibson.

23. Defendant Sandoz, Inc. (hereinafter "Sandoz") is a New Jersey corporation with a

principal place of business in New Jersey. Defendant Sandoz, Inc. regularly conducts business in Utah and throughout the United States and is involved in the manufacture, distribution, marketing, sale, labeling, and design of amiodarone in the State of Utah and throughout the United States as detailed below.

24. The Defendant conducts substantial, systematic continuous, and regular business in New Jersey, as well as throughout the United States and is involved in the distribution, marketing, sale, labeling, and design, of amiodarone in the State of New Jersey and throughout the United States as detailed below.

25. At all material times, upon information and belief, Defendant authorized and/or acted by and through its officers, employees, agents, servants, and/or representatives, including those actively engaged in the legal defense of Defendant.

26. At all material times, every reference made to any corporate Defendant in this Complaint includes predecessors, successors, parents, subsidiary, affiliates, and divisions of the corporation for the corresponding time period.

27. Whenever reference is made to any act, deed, or transaction of Defendant, the allegation means that the corporation engaged in the act, deed, or transaction by or through its officers, directors, agents, employees, or representatives while they were actively engaged in the corporation's management, direction, control, or business affairs. Any Defendant that is a subsidiary of a foreign parent acted as its parent company's agent for its parent's U.S. sales.

JURISDICTION AND VENUE

28. Venue is proper pursuant to 28 U.S.C. § 1391(b) because a substantial part of the events or omissions giving rise to the claim occurred within the District of Utah. The injuries at

issue in this lawsuit also occurred in the District of Utah.

29. Defendant conducts business in the District of Utah. Defendant's commercial activities in the District of include, but are not limited to, the marketing, sale and distribution of amiodarone.

30. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1331 and § 1332 due to the complete diversity of citizenship between Plaintiffs and Defendants, with the amount in controversy, exclusive of interest and costs, exceeding \$75,000.00.

FACTUAL BACKGROUND

31. All prescription drugs require approval by the Food and Drug Administration (hereinafter "FDA") before the drug may be marketed. Manufacturers of new drugs must submit a new drug application (hereinafter "NDA") to the FDA. An NDA must include information about the drug's safety and efficiency gleaned from clinical trials.³ It must also propose a label reflecting appropriate use, warnings, precautions, and adverse reactions.⁴

32. For generic drugs, Congress passed the Drug Price Competition and Patent Term Restoration Act in 1984. This statute amended the Food, Drug, and Cosmetic Act (hereinafter "FDCA") and is referred to as the Hatch-Waxman Amendments to the FDCA. The Hatch-Waxman Amendments provided an "abbreviated new drug application" (hereinafter "ANDA") procedure for generic manufacturers.⁵ Generic manufacturers are not required to repeat the clinical trials conducted by name brand manufacturers. ANDA's are approved based on the initial safety profile of the name brand drug and are subject to all post-marketing events and

³ 21 U.S.C. § 355(a)-(b).

⁴ 21 C.F.R. § 201.56.

⁵ 21 U.S.C. § 355(j).

post-sales events, including, but not limited to, collecting, tracking, and reporting adverse incident reports regarding the drug.

33. In 1985, brand manufacturer Wyeth received FDA approval⁶ to market and sell the anti-arrhythmic heart medication Cordarone® (amiodarone hydrochloride is the generic formulation) under a special “needs” approval without the usually mandated rigorous and FDA approved, double-blind, randomized clinical trials. Although the FDA has urged Wyeth to conduct randomized clinical trials, such trials have not been conducted. The FDA approval for Cordarone® remains a special and unusual “special needs” approval. The customary and rigorous randomized clinical trials now required by the FDA for all new drug applications have never been conducted for amiodarone. Wyeth was the initial manufacturer, promoter and distributor or “brand manufacturer” of Cordarone® in the United States.

34. Wyeth’s Cordarone® was approved only as a drug of last resort for patients suffering from documented recurrent life-threatening ventricular fibrillation and ventricular tachycardia when these conditions would not respond to other available anti-arrhythmic drugs and therapies. Wyeth aggressively and successfully marketed Cordarone® for inappropriate “off-label” uses as a “first line anti-arrhythmic therapy.”

35. Wyeth also instituted and maintained an active promotional campaign to physicians touting the anti-arrhythmic benefits of amiodarone; a campaign from which generic manufacturers such as Defendant still benefit. The campaigns focused on the use of the drug for atrial fibrillation and failed to warn prescribing physicians of the potential dangers associated with amiodarone toxicity and dangers to atrial fibrillation patients. Wyeth’s campaigns were

⁶ See NDA 18-972, Approval Letter, December 24, 1985.

pervasive and effective. The drug wrongfully became a first line therapy for atrial fibrillation because physicians were not warned of many of the potential dangers of the drug. In fact the brand manufacturer, Wyeth's fraudulent and misleading marketing campaigns resulted in warning letters from the FDA to stop the false and misleading promotion of the drug that downplayed the risks and promoted the drug as a first line anti-arrhythmic therapy.⁷ The FDA letters noted that it is unlawful for a manufacturer to promote any drug for a use not described in the approved labeling of the drug.⁸ The purpose of this federal requirement is to protect patients by ensuring drug manufacturers subject prospective uses of their drugs to randomize and well-controlled clinical trials to determine whether the drug is safe and effective for such uses. These requirements are meant to ensure that drug companies like Defendant, would give physicians and medical personnel trustworthy information so that medications are prescribed appropriately. Physicians may still prescribe drugs for unapproved uses. These unapproved uses are deemed "off-label" because they have not been approved by the FDA. (A pharmaceutical company is permitted to disseminate certain information about "off-label" uses, but such dissemination must adhere to strict requirements. For instance, the manufacturer must submit an application to the FDA seeking approval of the drug for "off-label" use; the manufacturer must provide its marketing materials to the FDA prior to dissemination; the materials must be in unabridged form; and the manufacturer must include disclosures that the materials pertain to an unapproved use of the drug, and, if the FDA deems it appropriate, "additional objective and scientifically

⁷ Warnings by the FDA to Wyeth began as early as 1988. <http://www.mcclatchydc.com/2003/11/04/28118/fda-oversight-of-off-label-drug.html>.

⁸ See 21 U.S.C. §§ 331(d), 352(f), and 355.

sound information . . . necessary to provide objectivity and balance.”⁹) The dissemination of information in violation of these provisions violates the Food, Drug and Cosmetic Act (hereinafter “FDC Act”).¹⁰ This law also requires pharmaceutical companies to furnish federal regulators with advance copies of any and all information they disseminate.¹¹ Any deviation from these requirements violates FDA regulations.

36. The brand manufacturer Wyeth received approval for the manufacture, marketing, sale and distribution of the generic formulation amiodarone hydrochloride in 1998.¹² As with all generic bioequivalent approvals, Defendant Sandoz was required by the FDA to provide patients prescribed the drug with all FDA approved labels, warnings and medication guides with information exactly as required of the brand formulation manufacturer, Wyeth, and as updated as directed by the FDA.¹³ Defendant took advantage of the pervasive brand innovator promotional activities of Wyeth and Defendant’s version of the drug directly benefited from the decades of marketing of the drug for “off-label” uses by Wyeth. The version of the drug produced by Defendant was also subject to the same advertising, marketing, and promotional requirements and restrictions set forth by the FDA for Wyeth in their advertising, marketing, and promotion of the drug Cordarone®. Defendant was required by the FDA to provide patients prescribed the drug with all FDA approved labels, warnings, and medication guides with information exactly as required of the brand formulation manufacturer, Wyeth, and as updated as

⁹ 21 U.S.C. § 360aaa, *et seq.*

¹⁰ 21 U.S.C. § 331(z).

¹¹ 21 U.S.C. § 360aaa.

¹² The approval letter noted on the FDA database is addressed to Copley Pharmaceutical, Inc. and dated November 30, 1998. http://www.accessdata.fda.gov/drugsatfda_docs/anda/98/74-739_Amiodarone_Approv.pdf.

¹³ *See* 21 U.S.C. § 355(j)(2)(A)(v); § 355(j)(4)(G).

directed by the FDA.¹⁴ In fact, the FDA letter to Wyeth, of which Defendant was well aware, also specifically referenced the on-going review and approval of any and all promotional materials for the drug as well as addressed the monitoring and reporting requirements of the manufacturer.¹⁵

37. As with all generic bioequivalent approvals, Defendant was required by the FDA to provide patients prescribed the drug with all FDA approved labels, warnings and Medication Guides with information exactly as required of the brand formulation manufacturer, Wyeth, and as updated as directed by the FDA.¹⁶ Defendant took advantage of the pervasive promotional activities of Wyeth. Defendant's generic version of the drug directly benefited from the marketing of the drug for "off-label" uses by Wyeth as well as its own promotional activities.¹⁷

38. Prior to being prescribed amiodarone, Ed Gibson was diagnosed with atrial fibrillation that was not deemed life threatening. Ed Gibson was not in a medical situation of "last resort" as to the management of his atrial fibrillation.

39. While acting as treating physician, and as a result of the continuing sales efforts of Defendant, Dr. Stephen Miller M.D. prescribed Ed Gibson to take a 90-day course of 200mg amiodarone tablets for treatment of non-life threatening atrial fibrillation. Ed Gibson filled the prescription and ingested the drug amiodarone according to the instructions.¹⁸ Ed Gibson was not aware that his use of the medication was for an "off-label" use and, as noted above, he was not in a situation of last resort as to his atrial fibrillation. More importantly, Ed did not receive

¹⁴ See 21 U.S.C. § 355(j)(2)(A)(v); § 355(j)(4)(G).

¹⁵ See Application 75-188 Approval Letter to Robert A. Fermia dated February 24, 1999.

¹⁶ See 21 U.S.C. § 355(j)(2)(A)(v); § 355(j)(4)(G).

¹⁷ See Application 75-188 Approval Letter to Robert A. Fermia dated February 24, 1999.

¹⁸ LDS Hospital Pharmacy; NDC number 00781120360; Sandoz Pharmaceuticals Corporation.

the required Medication Guide from Defendant for the prescriptions he filled at the Pharmacy at LDS Hospital. Ed did not receive the Medication Guide from his pharmacist because the Medication Guides were not provided by the Defendant to the distributors and pharmacists for distribution to Ed with his prescription. Because he did not receive the Medication Guide, Ed received and ingested a mislabeled drug. Correction of atrial fibrillation was never an FDA approved use of Cordarone® or its bioequivalents, and Ed's prescription was for an "off-label" use and without the benefit of the FDA mandated Medication Guide. Ed was unaware of the dangers he faced from the drug that caused his injuries.

40. The prescription for the amiodarone tablets Ed Gibson received were marked with the numbers 00781-1203-60 which identified the tablets as manufactured, marketed and distributed by Sandoz, Inc. The amiodarone ingested by Ed was the generic version of Wyeth's Cordarone®. This "off-label" prescription and distribution of the drug to control a non-life threatening atrial fibrillation, also a direct result of the long term promotional efforts of Defendant and without the required Medication Guide, was a producing and proximate cause of Ed Gibson's injuries and death from amiodarone toxicity.

41. Ed was not aware that his use of the medication was for an "off-label" use and, as noted above, he was not in a situation of last resort as to his atrial fibrillation. More importantly, he did not receive the required Medication Guide from Defendant for the prescriptions he filled at the pharmacy.

42. Ed Gibson was prescribed and given Amiodarone, as an outpatient at LDS Hospital in Salt Lake City. LDS Hospital did not provide him with the Medication Guide.¹⁹ LDS

¹⁹ The FDA requires that Medication Guides be issued with certain prescribed drugs and biological products when

Hospital did not provide it because Sandoz did not provide Medication Guides to LDS Hospital, rendering the drug illegal for sale. Sandoz was responsible for ensuring that the Medication Guide was provided to Ed Gibson. Had he been provided the Medication Guide, he would have been aware of the serious lung related side effects that could lead to death as well as other issues and he would not have taken Amiodarone. The FDA requires that a medication guide must be provided to a patient or a patient's agent when a drug is dispensed in an outpatient setting (e.g., retail pharmacy, hospital ambulatory care pharmacy) and the product will then be used by the patient without direct supervision by a healthcare professional.²⁰ Ed would not have taken amiodarone and would not have died from amiodarone toxicity had he received the required Medication Guide.

43. The serious side effects outlined in the Medication Guide, all of which Ed experienced after taking amiodarone, included lung damage, shortness of breath, wheezing, trouble breathing, coughing, tiredness, weakness, nervousness, irritability, restlessness, decreased concentration, and depression.²¹

44. Because his distributor and pharmacist were not provided a Medication Guide to provide to him with his prescriptions by the Defendant manufacturer, Ed did not know that amiodarone "should only be used in adults with life-threatening heartbeat problems called ventricular arrhythmias" and even then when "other treatments did not work or were not

the Agency determines that certain information is necessary to prevent serious adverse effects; patient decision-making should be informed by information about a known serious side effect with a product, or patient adherence to directions for the use of a product are essential to its effectiveness. <http://www.fda.gov/Drugs/DrugSafety/ucm085729.htm>.

²⁰ FDA Guidance for Medication Guides – Distribution Requirements and Inclusion in Risk Evaluation and Mitigation Strategies (REMS). <http://www.fda.gov/downloads/Drugs/.../Guidances/UCM244570.pdf>.

²¹ Medication Guide for amiodarone HCl. <http://www.fda.gov/downloads/Drugs/DrugSafety/UCM152841.pdf>.

tolerated.”²² He did not know that any other use such as the use for his atrial fibrillation was considered to be “off-label” and Ed did not know of the corresponding dangers associated with such uses.

45. Because his distributor and pharmacist were not provided a Medication Guide to give directly to him outside of his doctor’s office and interaction as required by FDA regulations by the Defendant manufacturer, Ed did not know “the medicine stays in your body for months after treatment is stopped.”²³ The effects of amiodarone are extremely long lasting. Amiodarone is fat-soluble, and tends to concentrate in tissues including fat, muscle, liver, lungs, and skin and confers a high volume of distribution and a long half-life; the amount of time it takes for one-half of an administered drug to be lost through biological processes (metabolism and elimination). Because of this long half-life, amiodarone’s dangerous properties continue to cause injuries in patients such as Ed Gibson long after he ceased using the drug, including, serious pulmonary injuries. This information was unknown to Ed due to the failure of the Defendant manufacturer to provide the Medication Guide to the distributor.

46. Each manufacturer who ships a container of an FDA approved drug product for which a Medication Guide is required is responsible for ensuring that Medication Guides are available for distribution directly to patients with each prescription.²⁴ Defendant Sandoz is a manufacturer as defined by the FDA and is required to provide the Medication Guides to the distributors so that the distributors can provide the Medication Guides to pharmacists who then can provide the Medication Guides directly to the patient. The FDA has recognized that “it is

²² Medication Guide for amiodarone HCl. <http://www.fda.gov/downloads/Drugs/DrugSafety/UCM152841.pdf>.

²³ Medication Guide for amiodarone HCl. <http://www.fda.gov/downloads/Drugs/DrugSafety/UCM152841.pdf>.

²⁴ See 21 CFR § 208.24.

important that patients receive appropriate risk information in the form of Medication Guides in order to make informed decisions about certain prescribed medications.” The Medication Guides are to specifically provide information directly to the patient outside of the interaction with the physician. It is important to note that the FDA has mandated that the warnings included in the Medication Guides go directly to the distributor and via the distributor and pharmacists directly to the patient as an important notification distributed outside and in addition to any warning or information that is provided by the physician. Drugs identified by the FDA for the Medication Guide procedure are significantly dangerous to such a degree that the FDA requires a warning outside of information provided directly by the physician. The FDA has expressed concern at the failure of drug manufacturers in the distribution of the Medication Guides to the distributors and that “the current Medication Guide program is too cumbersome and that it lacks a standard distribution system.” Failure to provide the Medication Guide results in the distribution of a mislabeled and illegal drug.

47. The National Consumer Pharmacy Association has also identified the failure of manufacturers to ensure the distribution of Medication Guides to distributors and thus to the patients as a significant safety issue and called on the FDA to “enforce current FDA MedGuide regulations holding manufacturers accountable for providing Medication Guides in sufficient number or the means to produce Medication Guides in sufficient number, to permit the authorized dispenser to provide a Medication Guide to each patient who receives a prescription for the drug product.”²⁵ Ed did not receive a Medication Guide because the Defendant Sandoz did not provide the Medication Guide to the distributor for distribution to him by his pharmacist

²⁵ Use of Medication Guides to Distribute Drug Risk Information to Patients, Colleen Brennan, RPh; Bryan Ziegler, PharmD, MBA.

as required by the FDA and did not ensure that the Medication Guide was distributed to Ed Gibson.

48. After taking amiodarone, Ed experienced many of the symptoms outlined in the Medication Guide to include shortness of breath, wheezing, trouble breathing, coughing, tiredness, weakness, nervousness, irritability, restlessness, decreased concentration, and depression.

49. At the time Ed Gibson was prescribed amiodarone, he was perfectly healthy following a successful open heart surgery, for a genetic condition. This hereditary heart condition did not cause Ed Gibson's life to be in danger, and did not put him in a situation of last resort. At this time, Gibson was in shape, self-dependent, and lived an active lifestyle. He was single and owned his own construction company. He was regularly able to engage in rigorous physical activities such as pouring concrete.

50. Ed's condition continued to deteriorate. He experienced increasing pulmonary issues to include shortening of breath, deep cough and difficulty in doing the things that he always enjoyed at home. He was taken off the drug in 2006.

51. Ed Gibson died on September 23, 2014. At the time of his death, Ed Gibson was a 68-year-old resident of Eagle Mountain, Utah. Amiodarone Toxicity, amiodarone induced lung disease was the cause of death.

52. At all material times, amiodarone caused and contribute to severe and disabling medical conditions and death, such as those experienced by Ed Gibson, including, without limitation, the following: pulmonary toxicity, pulmonary fibrosis, hepatic damage and failure, neurotoxicity, neonatal hypothyroidism, birth defects, optic neuritis, toxic optic neuropathy,

blindness, peripheral neuropathy, heart damage and failure, hypotension, serious exacerbation of arrhythmias, and congestive heart failure.

53. Upon information and belief, Defendant, has received information concerning deaths and serious injury resulting from the use of amiodarone.

54. Upon information and belief, Defendant has received information concerning cases of severe medical conditions resulting from the use of amiodarone, including, without limitation, pulmonary toxicity, pulmonary fibrosis, lung damage, hepatic damage and failure, neurotoxicity, peripheral neuropathy, neonatal hypothyroidism, optic neuritis, toxic optic neuropathy, blindness, serious exacerbation of arrhythmias, and congestive heart failure such as that experienced by Ed Gibson.

55. Healthcare providers, as well as patient-consumers reported these events, upon information and belief, directly to the company.

56. In addition to these direct notices of adverse events, the FDA had, and continues to have, in effect, an adverse reaction surveillance system for all regulated drugs, including amiodarone, called the Adverse Event Reporting System (AERS).

57. Upon information and belief, the AERS has placed Defendant on notice of numerous instances of catastrophic injuries caused by ingestion of amiodarone.

58. At all material times, Defendant failed to disclose to the FDA, healthcare professionals, consumers, or Ed, of the information they possessed concerning the incidents and actual adverse medical events, injuries, and deaths suffered by amiodarone users. Instead, upon information and belief, the Defendant actively took advantage of the promotional efforts of innovator brand drug manufacturer Wyeth, for “off-label,” unapproved uses as described herein

through various means as well as its own efforts, including, but not limited to, the following:

- m. Direct-to-physician and direct-to-pharmacist promotion through sales representatives;
- n. Promotion through funding and manipulation of so-called “educators” who organize and arrange continuing medical education (CME) courses for physicians and pharmacists;
- o. Formulation of unlawful conspiracies with certain medical marketing and medical “education” entities to promote – without appearing to promote – “off-label” uses;
- p. Sponsorship and funding of the production of CME materials;
- q. Cultivation and development of so-called “opinion leaders” in local medical communities and support for the careers and research of those physicians, pharmacists, and researchers who advocate off-label uses;
- r. Sponsorship of journal supplements and symposia on “off-label” uses;
- s. Placing (through sponsorship of limited trials, studies, and surveys) of medical literature databases showing positive effects (already established) on risk factors with the twin purposes of overwhelming any independent study showing negative effects on different risk factors, and causing earnest but time-crunched physicians to be impressed with the sheer quantity of favorable (but redundant) studies on MedLine, or medical library, search;
- t. Media advertisements and brochures, some of which were disguised as “educational materials”;
- u. Coordination of physician-to-physician interactions that are biased toward “off-label” usages;
- v. Internet listings that omit important warnings and information; and
- w. Various other forms of marketing and promotion.

59. Upon information and belief, in accepting the benefits of brand innovator Wyeth’s efforts in promoting “off-label” uses of Cordarone® by sponsoring CME conferences and materials, journal supplements, redundant trials, and the work and careers of favorably disposed

opinion leaders, Defendant would sometimes escape disclosure for any role at all in the presentation of its desired view.

60. Additionally, upon information and belief, Sandoz and/or their agents' pharmaceutical sales representatives and materials and sources actively promoted their generic amiodarone in the stream of commerce for the "off-label" uses openly promoted by Wyeth.

61. At all material times, despite FDA warnings and thousands of adverse patient experiences, Defendant continued their fraudulent marketing, promotional, and sales practices through the present date.

62. At all material times, Defendant concealed information about catastrophic injuries and death, and thousands of serious adverse medical events from the FDA, health care professionals, and consumers, including Ed Gibson.

63. At all material times, the amiodarone, manufactured and/or supplied by Defendant was and is unaccompanied by proper warnings regarding all possible adverse side effects and comparative severity and duration of such adverse effects; the warnings given did not and do not accurately reflect the severity or duration of the adverse side effects or the true potential and/or likelihood or rate of the side effects. This is particularly so with regard to "off-label" use.

64. At all material times, Defendant failed to warn of material facts regarding the safety and efficacy of amiodarone.

65. For example, although Defendant knew, should have known, and currently knows that the majority of patients consuming amiodarone are older, including those aged 55 and over such as Ed, Defendant has failed and refused to conduct testing, studies, surveys, and/or report the results of same regarding amiodarone use in this age group.

66. At all material times, the amiodarone manufactured, distributed, and/or supplied by Defendant was defective due to inadequate post-marketing warning and instruction because, after Defendant knew or should have known of the risk of injury from amiodarone, especially in “off-label” use, Defendant failed to provide adequate and required warnings to physicians, users or consumers of amiodarone, including the Plaintiff Ed Gibson, and continued to aggressively sell amiodarone, including for “off-label” use.

67. At all material times, while Defendant concealed this adverse event information, they simultaneously engaged in a massive and fraudulent marketing and promotional scheme in which they aggressively and fraudulently promoted amiodarone for uses never authorized by the FDA. In fact, Defendants marketed, promoted, and “pushed” amiodarone, not as a drug of last resort, but as a drug suitable as an initial therapy and to treat non-life-threatening heart conditions.

68. At all material times, Defendant respectively, also promoted amiodarone for heart conditions less severe than life-threatening ventricular arrhythmia (the only purpose for which the drug originally received FDA approval).

69. Defendant engaged in a conspiracy of silence regarding “off-label” use, choosing to market and promote the drug for “off-label” use, and then feigning ignorance before the FDA, health care providers, and consumers. They failed and refused to conduct thorough testing on the side effects, despite knowing that their scheme to promote the drug for “off-label” uses had been, and continues to be, successful.

70. Defendant has engaged in this calculated and coordinated silence despite their knowledge of the growing public acceptance of misinformation and misrepresentations regarding

both the safety and efficacy of the use of amiodarone, and did so because the prospect of significant future profits outweighed their concern regarding health and safety issues, all to the significant detriment of the public and Ed Gibson.

71. At all material times, Defendant's affirmative misrepresentations and omissions have so infected the market in the United States that physicians and consumers relied on Defendant's fraud, respectively, to the detriment of their patients and themselves.

72. Nevertheless, at all material times, the warnings for amiodarone, in effect during the relevant time period were vague, incomplete, and/or otherwise wholly inadequate, both substantively and graphically, to alert prescribing physicians, pharmacists, consumer patients and Ed Gibson of the actual risks associated with this drug.

73. At all material times, Defendant's deception, concealment, and fraudulent marketing and promotion has been so pervasive throughout the United States, that prescribing physicians and consumer patients have during the relevant time period still believe that amiodarone, is an acceptable initial, secondary, or otherwise early-stage anti-arrhythmic intervention. These deceptive techniques served (and continue to serve) Defendant in several ways, including: (1) instilling Defendant's desired view about the drug's "off-label" uses among health care providers; (2) Defendant hoped that, by concealing its agency in these activities, they would escape the legal ramifications of its unlawful promotional activities; and (3) boost Defendant's profits for the drug.

74. At all material times, Defendant, owed a duty to the health care providers, consumer patients, and Ed herein, to engage in honest and non-deceptive practices; exercise due care under the circumstances, to exercise due care in the design, manufacture, marketing,

promotion, sale, and distribution of amiodarone; to provide a reasonably safe and non-defective drug; to provide adequate and appropriate warnings for said drug; to comply with federal guidelines, rules, and regulations; and/or to sell and distribute the drug in accordance with FDA restrictions.

75. At all material times, Defendant marketed amiodarone, as having approval, characteristics, uses, and benefits that the drug did not have.

76. At all material times, Defendant, did design, create, test, develop, label, sterilize, package, manufacture, market, promote, advertise, distribute, sell, warn, and/or otherwise caused the product to be placed into the stream of commerce, and ultimately to be ingested by Samir.

77. At all material times, Defendant willfully failed and refused to actively and affirmatively monitor amiodarone's "off-label," unapproved uses insofar that such uses caused catastrophic injuries and death. Defendant however, continued to sell amiodarone for unapproved uses.

78. At all material times, Defendant engaged in a continuing course of fraud, concealment, material nondisclosure and omission, upon Plaintiffs which prevented Plaintiffs from knowing or having reason to know of Defendant's misconduct.

A. AMIODARONE DID NOT UNDERGO THE RIGOROUS FDA APPROVAL PROCESS REQUIRED FOR FEDERAL PREEMPTION

79. Brand manufacturer Wyeth introduced Cordarone® into the United States' stream of commerce. Wyeth received approval for Cordarone® from the FDA only as a drug of last resort for patients suffering from documented recurrent life-threatening ventricular fibrillation and ventricular tachycardia; and further, only when these conditions would not respond to other available anti-arrhythmic drugs and therapies. Furthermore, despite repeated requests by the

FDA at the outset of the review process and throughout the history of the drug, neither Wyeth, Upshaw the maker of the “other” brand name version of amiodarone or the generic drug manufacturers of the product have submitted the drug to the rigorous randomized clinical trials required for FDA drug approval.

80. Amiodarone as the drug is commonly known was developed in Belgium in the 1960’s as a drug for treating a common heart condition known as angina. At that time, amiodarone was released for marketing in most countries OTHER than the United States.

81. The misunderstanding and use of amiodarone as a drug “with little side effects” became widespread except in the United States. In the 1970’s American Doctors began obtaining amiodarone from Canada and Europe for use in their patients with life-threatening arrhythmias who did not respond to other drugs. This activity was sanctioned by the FDA but only on a limited basis. Initial results were promising and by the mid-1980’s literally tens of thousands of Americans were taking the drug without FDA approval or testing. American doctors apparently monitored the conditions of their patients more rigorously than their colleagues around the world because they found the drug produced a bizarre series of side effects that doctors around the world seemed to have missed and that were not caught because of the lack of testing or randomized trials.

82. The FDA was essentially forced to release amiodarone for marketing in the United States by the mid-1980’s when foreign manufacturers of the drug threatened to cut off the supply to Americans after having supplied the drug for free to thousands of Americans for over five years.

83. As a result, unlike any other drug in modern history, amiodarone became FDA

approved without rigorous, FDA sanctioned randomized clinical trials. The legal reasons for preemption applied to drug litigation for FDA approved drugs are not present in amiodarone. Amiodarone has never been subjected to double blind testing as mandated by the FDA.

84. Amiodarone has been determined to affect many different organs in many ways. First, the drug takes many weeks to achieve the maximum effectiveness. Amiodarone is literally “stored” in most of the tissues of the body and to “load” the body with the drug all the tissues need to be saturated. Therefore, the typical loading regimen of amiodarone is to use extremely large dosages of the drug for the first week to two weeks then to taper the dosage over the next month. It is not unusual to give a patient 1200 to 1600 mg dosage a day when starting the drug and to maintain the patient on as little as 100 to 200 mg per day on a chronic basis.

85. Amiodarone leaves the body very slowly. The drug is not excreted like most drugs through the liver or kidney but is only lost when amiodarone containing cells such as skin cells or cells from the GI tract are lost. Therefore, even when it is decided that the patient needs to stop taking amiodarone the drug remains in the system in measurable quantities for months and even years.

86. Most importantly, because the drug is stored in many different types of tissues it can cause side effects that affect many different types of organs. Some of the side effects take months and years to develop. Constant diligence is needed.

87. Amiodarone causes many horrific side effects that have resulted in its restricted use in the United States including; causing blindness, it causes deposits to form on the cornea of the eyes, a condition in virtually everyone who takes the drug; amiodarone causes a very disfiguring blue-grey discoloration of the skin, generally in areas of exposure to the sun;

amiodarone often sensitizes the skin to sunlight so that even trivial exposure results in severe sunburns; amiodarone causes hypothyroidism-low thyroidism, - a condition relatively easy to treat with thyroid medication. Some patients develop hyperthyroidism-high thyroid, which is more dangerous and more difficult to treat. Amiodarone can cause liver toxicity; therefore, liver enzymes need to be monitored periodically. Amiodarone can cause severe gastric reflux, caused by a paralysis of the sphincter at the end of the esophagus.

88. The most serious side effect of amiodarone and the one requiring the patient Medication Guide is pulmonary toxicity-lung disease. Amiodarone produces two types of lung disease-first, acute pulmonary syndrome, which looks and acts like typical pneumonia, with a sudden onset of cough and shortness of breath, a condition that rapidly improves once the amiodarone is stopped. The second type is more dangerous. This condition involves a gradual, almost unnoticeable, stiffening of the lungs that both the doctor and patient overlook until finally severe irreversible lung damage is done. This condition can occur quickly after the taking of the drug or can occur years after the drug has begun. Lung toxicity has been found by the FDA to be 17% and fatalities from pulmonary toxicity have been found to be 10% of those taking the drug. These statistics come from those taking the drug for conditions the drug is not approved for-arterial fibrillation, as well as the ventricular condition it is approved for as a drug of last resort after other treatments have been tried and have failed.

89. Amiodarone did not undergo the rigorous clinical randomized trials all other FDA approved drugs other than a few “grandfathered” drugs with long market histories have undergone. Despite repeated requests, demands and even threats from the FDA the manufacturers of amiodarone and its FDA labeled “brand-names” Wyeth’s Cordarone and

Upshaw's Pacerone®, have never undergone the type of clinical trials that would show its defects or the benefits verses the risks associated with the drug's use. Despite the economic argument that the patent has expired, or that the costs of testing is too high to justify the investment amiodarone continues to generate enormous revenues for the drug manufacturers without the public having the protection of FDA randomized clinical trials.

90. The only trials amiodarone underwent were non-scientific, reporting of a combination of various patient results combined to obtain statistical data that is neither randomized or reliable and which interestingly enough did not even provide the statistical data that has been determined by the FDA to be accurate for the drug and required in the black box labeling of the product. Obviously, this combination of reporting of various patients was non-scientific and cannot serve as the basis for a claim of preemption.

91. Without rigorous, scientific, clinical trials and randomized testing approved by the FDA the reasons for FDA preemption do not exist and cannot be sustained. Neither the so-called 'brand names' or the generic versions of the drug offer any protection to the public from the FDA approval process. Since the manufacturers will not undergo FDA approved testing they cannot use the FDA approval process as a shield from liability when sued. None of the reasons articulated by the United States Supreme Court for the protection preemption provides are present with amiodarone. None of the costs benefits analysis is present. In addition, none of the regulatory analysis argument and certainly no Federalism argument are present to support preemption.

92. This is not to say the FDA completely disregarded its regulatory or enforcement powers regarding amiodarone. While no testing justifying preemption was ever performed, when

the statistical evidence of the dangers of amiodarone and its many side effects became known, the FDA repeatedly amended the labeling requirements for amiodarone, mostly resulting from public pressure and enacted a requirement that the drug manufacturer directly provide the patient a FDA approved “Medication Guide” by ensuring distribution of the Medication Guides to the distributors and then to the patient along with the drug. Due to the failure to conduct required randomized clinical testing by the Defendants, Plaintiff is not preempted from claiming the Defendants illegally marketed the product for “off-label” use, and is not preempted from claiming that the product itself is unreasonably dangerous as it was packaged, marketed, designed, manufactured and sold. Most importantly, Plaintiff is not preempted from claiming Defendants failed to warn of the dangers of the product by failing to provide the FDA required “Medication Guide” consisting of ONLY language the FDA approved to go directly to the patient. The failure to provide the FDA “Medication Guide” is a stronger claim than merely alleging the package insert or labeling fails to inform or warn patients or consumers of the dangers of the product. The failure to provide each patient a “Medication Guide” by failing to provide the Medication Guides to the distributor for ultimate distribution to the patient with the drug is a direct violation of the FDA’s mandate to the manufacturers of the drug intended to warn patients directly outside the communication with the prescribing physician, of the very dangers of amiodarone toxicity that killed Ed Gibson.

**FIRST CAUSE OF ACTION
(Wrongful Death)**

93. Plaintiff incorporates by reference all other paragraphs of this Complaint as if full set forth herein.

94. The death of Ed Gibson was directly and proximately caused by the negligent actions of the Defendant as related to the manufacture, marketing, distribution and sale of Amiodarone as described herein.

**SECOND CAUSE OF ACTION
(Gross Negligence)**

95. Plaintiff incorporates all previous paragraphs.

96. Despite the FDA including requirements for “Black Box” warnings about the dangers of Amiodarone and its brand name equivalent, the FDA recognized that too many patients were dying from ingesting this drug. The manufacturers were hiding the “Black Box” on package inserts that were forty to fifty pages, included the chemical make-up of the drug and were never read or contained in the PDR (Physician’s Desk Reference) and physicians had been influenced more by the drug companies marketing and sales scheme, than the warnings. Patients were not being told of the drugs dangers and were dying.

97. For only the 60th time in its history of drug approval and regulation making, the FDA made a rule making decision requiring that “THE MANUFACTURER” of the brand name or generic drug amiodarone provide to the patient ingesting the drug a MEDICATION GUIDE with FDA approved warning that could not be added to or subtracted from by the drug companies.

98. Despite the FDA requirements that the drug companies provide the patients medication guide with FDA written material with their Amiodarone prescription, no Medication Guide was provided to Ed Gibson by Defendant.

99. If Ed Gibson had been provided the Medication Guide he would not have taken Amiodarone for a non-life threatening, non-last resort condition – atrial fibrillation, and he would still be alive today.

100. According to the CVS, Costco, OptumRx, and Walgreens, Defendant was not and is not providing them or the patients with Medication Guides.

101. Defendant is guilty of gross negligence for failure to provide the FDA-required Medication Guide.

102. The failure to provide the Medication Guide is a direct and proximate cause of Plaintiff's damages, and also warrants punitive damages.

**THIRD CAUSE OF ACTION
(Off-Label Marketing)**

103. Plaintiff incorporates all previous paragraphs.

104. Upon information and belief, ninety (90%) percent of the Amiodarone/Cordorone prescriptions written in the United States are written for “arterial-fibrillation,” a non-FDA approved use of the drug. When a drug is prescribed by a number of physicians for a non-approved condition, courts can look at the percentage of prescriptions written for the non-FDA condition in order to allow discovery on the issue of off-label promotion.

105. The percentage (90%) of prescriptions of Amiodarone/Cordorone written for non-life-threatening conditions – for a drug with a 10% fatality rate and 17% toxicity rate – is astounding, and it is beyond belief that Defendant was unaware of this. Without off-label promotions, schemes or encouragement, it is inconceivable that caring physicians would continuously write these prescriptions, not only subjecting their non-life-threatened patients to death from the drug but to a *horrific* death, one caused by “Amiodarone toxicity” or pulmonary

fibrosis where the patient is unable to breath, coughs, wheezes, struggles to catch their breath or get enough air into their lungs and eventually for humanitarian reasons is placed on morphine until they stop breathing.

106. Plaintiff contends that the off-label use of Amiodarone was promoted by Sandoz and the other drug manufacturers illegally, but in such a manner as to escape FDA regulation. Despite repeated admonitions by the FDA and continuous label changes, the FDA's only solution to the problem was adoption of the required Medication Guide to replace the package inserts, direct physician marketing, and other communication means controlled by the drug industry.

107. On information and belief, the off-label marketing and promotion of Amiodarone by Defendant proximately caused Ed Gibson's horrific death. Ed Gibson's physician, Dr. Stephen Miller, like the other doctors writing prescriptions for Amiodarone for use as a first line drug for arterial fibulation, was influenced by Defendants' long term and successful promotional efforts, and those efforts likely affected her decision to prescribe Amiodarone to Ed Gibson. Because of the secrecy in the drug manufacturing industry, given the billions of dollars at stake, and the likely related lack of whistleblowers, Plaintiff, and those similarly situated, must be granted the right to pursue discovery to support their claims. Otherwise, Wyeth, and other manufacturers, will escape liability not because they are not liable, but because Plaintiff was unable to access the door to justice.

**FOURTH CAUSE OF ACTION
(Negligence Per Se)**

108. Plaintiff incorporates all previous paragraphs.

109. FDA regulations required Defendant to provide each patient prescribed Defendant's Amiodarone with a Medication Guide, and nothing else. By both (1) failing to provide a Medication Guide, and (2) providing a packaging insert, Defendant rendered the sale of its Amiodarone to Plaintiff (and others) illegal, and is guilty of negligence per se. Defendant's negligence per se is the proximate cause of Plaintiff's damages, and constitutes gross negligence, allowing for punitive damages.

WHEREFORE, Plaintiff demands judgment against Defendant for compensatory damages and punitive damages, together with applicable interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

DEMAND FOR JURY TRIAL

Plaintiff in the above-styled case hereby demands a trial by jury of all issues so triable as a matter of right.

DATED: May 25, 2016.

ANDERSON & KARRENBURG

/s/ Thomas R. Karrenberg

Thomas R. Karrenberg

Jared D. Scott

Attorneys for Plaintiffs